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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Aldo T. Iacono

Serial No. : 09/244,792 Art Unit: 1614

Filed : February 5, 1999 Examiner: Travers, R.

For : USE OF AEROSOLIZED CYCLOSPORINE FOR
PREVENTION AND TREATMENT OF PULMONARY
DISEASE

INFORMATION DISCLOSURE STATEMENT

I hereby certify that this paper is being deposited with the United States
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January 11, 2000

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Carmella L. Stephens

Attorney Name

41,328

PTO Registration No.

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January 11, 2000

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Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure imposed by 37 C.F.R. § 1.56, to
inform the Patent Office of all references coming to the attention of the individuals
associated with the filing or prosecution of the above-mentioned application that are or
may be material to the patentability of the subject application, Attorneys for Applicants

hereby direct the Examiner's attention to the following references which have been arranged in reverse chronological order.

1. Oates, et al, 1987 *Drug Therapy: Cyclosporine*, New England Journal of Medicine 321:1725-1738
2. Glanville, et al, 1987, *Obliterative Bronchiolitis after Heart-Lung Transplantation: Apparent Arrest by Augmented Immunosuppression*, Annals of Internal Medicine 107:300-304
3. Kumar, et al, 1988, *Correlation of Blood Levels and Tissue Levels of Cyclosporine with the Histologic Features of Cyclosporine Toxicity*, Transplantation Proceedings 20:407-413
4. Burckart, et al, 1989, *Cyclosporine Administration by Aerosol*, J. Clin. Pharmacol 29:832-862
5. Stepkowski, S., et al, 1989, *Prolongation of Heterotopic Heart Allograft Survival by Local Delivery of Continuous Low-Dose Cyclosporine Therapy*, Transplantation 47:17-23
6. Dowling, et al, 1990, *Aerosolized Cyclosporine as Single-Agent Immunotherapy in Canine Lung Allografts*, Surgery, 108:198-205
7. Lin, et al., 1990, *Experimental Heterotopic Heart Transplantation without Ischemia or Reperfusion*, J. Heart Transplantation, 9:720-723
8. Miller and Mason, 1991, *Aerosol Deposition of a Propylene Glycol Solution*, Journal of Aerosol Medicine, 4:293-296
9. Copeland and Yatscoff, 1991, *The Isolation, Structural Characterization, and Immunosuppressive Activity of Cyclosporin G (Nva²-Cyclosporine) Metabolites*, Therapeutic Drug Monitoring, 13:281-288
10. Zenati, M., et al, 1990, *Immunosuppression with Aerosolized Cyclosporine for Prevention of Lung Rejection in a Rat Model*, Eur. J. Cardio-thorac Surg., 5:266-272

11. O'Riordan, et al, 1992, *Production of an Aerosol of Cyclosporine as a Prelude to Clinical Studies*, Journal of Aerosol Medicine, 5:171-177
12. Keenan, et al, 1992, *Improved Immunosuppression with Aerosolized Cyclosporine in Experimental Pulmonary Transplantation*, Transplantation, 53:20-25
13. Griffith, et al., 1992, *Acute Rejection of Lung Allografts with Various Immunosuppressive Protocols*, Society of Thoracic Surgeons, 54:846-51
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15. Trulock, 1993, *Management of Lung Transplant Rejection*, Chest, 103:1566-1576
16. Kesten, et al, 1995, *Treatment of Presumed and Proven Acute Rejection Following Six Months of Lung Transplant Survival*, Am J Respir Crit Care Med, 152:1321-1324
17. Keenan, et al., 1995, *Efficacy of Inhaled Cyclosporine in Lung Transplant Recipients with Refractory Rejection: Correlation of Intragraft Cytokine Gene Expression with Pulmonary Function and Histologic Characteristics*, 1995 Surgery 118:385-391
18. Ko, et al., 1995 J Jpn Surg. Soc. 96:160-167
19. Iacono, et al., 1996, *Aerosolized Cyclosporine in Lung Recipients with Refractory Chronic Rejection*, Am J Respir Crit Care Med, 153:1451-1455
20. Valentine, et al., 1996, *Total Lymphoid Irradiation for Refractory Acute Rejection in Heart-Lung and Lung Allografts*, Chest, 109:1184-89
21. Cahill, et al., 1996, *Methotrexate for Lung Transplant Recipients with Steroid-Resistant Acute Rejection*, J. Heart and Lung Transplantation, 15:1130-1136
22. Iacono, et al., 1997, *Dose-Related Reversal of Acute Lung Rejection by Aerosolized Cyclosporine*, Am J Respir Crit Care Med, 155:1690-1698
23. Keenan, et al., 1997, *Treatment of Refractory Acute Allograft Rejection with Aerosolized Cyclosporine in Lung Transplant Recipients*, J. Thoracic and Cardiovascular Surgery, 113:336-341

24. Iacono, et al., 1997, *Interleukin 6 and Interferon- γ Gene Expression in Lung Transplant Recipients with Refractory Acute Cellular Rejection*, *Transplantation* 64:263-269
25. Mitruka, et al., 1998, *Aerosol Cyclosporine Prevents Acute Allograft Rejection in Experimental Lung Transplantation*, *Journal of Thoracic and Cardiovascular Surgery* 115:28-37

Identification of the above-listed references is not to be construed as an admission of the Applicants or attorneys for Applicants that such references are available as "prior art" against the subject application. The referenced citations are listed on the accompanying PTO form 1449 and copies of the above-listed references are provided.

Applicants respectfully request that the Examiner review the foregoing references and that the references be made of record in the file history of the above-captioned application.

A check in the amount of \$240.00 to cover the fee required for filing of an Information Disclosure Statement after the mailing date of a first Office Action on the merits is enclosed. Please charge our Deposit Account No. 02-4377 if there is any additional fee required. Two copies of this sheet are enclosed.

Respectfully submitted,

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Enclosures (PTO Form 1449; References)